

Eur J Vasc Endovasc Surg 32, 537–541 (2006)

doi:10.1016/j.ejvs.2006.05.013, available online at <http://www.sciencedirect.com> on  ScienceDirect

Duplex Ultrasound Scanning is Reliable in the Detection of Endoleak Following Endovascular Aneurysm Repair

R.M. Sandford,* M.J. Bown, G. Fishwick, F. Murphy, M. Naylor, Y. Sensier,
R. Sharpe, J. Walker, T. Hartshorn, N.J. London and R.D. Sayers

Vascular Surgery Group, Department of Cardiovascular Sciences, University of Leicester,
Level 2 RKCSB, Leicester Royal Infirmary, Leicester LE2 7LX, United Kingdom

Objective. To investigate the value of duplex ultrasound scanning (DUSS) in the routine follow up of patients following EVAR.

Methods. Imaging was reviewed for 310 consecutive patients undergoing EVAR at a single centre. Concurrent ultrasound and CT scans were defined as having occurred within 6 months of each other. There were 244 paired concurrent DUSS and CT scans which were used for further analysis. These modalities were compared with respect to sensitivity, specificity, positive and negative predictive values and level of agreement (by Kappa statistics) using CT as the 'gold standard'.

Results. DUSS failed to detect a number of endoleaks which were seen on CT and the sensitivity of this test was therefore poor (67%). However, the specificity of DUSS compared more favourably with a value of 91%. Positive predictive values ranged from 33–100% but negative predictive values were more reliable with values of 91–100% at all time points post operatively. There were no type I leaks, or endoleaks requiring intervention which were missed on DUSS. Overall, there was a 'fair' level of agreement between the two imaging modalities using Kappa statistics.

Conclusion. Although DUSS is not as sensitive as CT scanning in the detection of endoleak, no leaks requiring intervention were missed on DUSS in this study. DUSS is much cheaper than CT and avoids high doses of radiation. DUSS therefore remains a valuable method of follow up after EVAR and can reduce the need for repeated CT scans.

Keywords: Aneurysm; Endovascular; Follow-up; Endoleak.

Introduction

Endovascular aneurysm repair (EVAR) has increased in popularity since it was first described in 1991.¹ The interim results from the EVAR 1 and DREAM trials reported improved perioperative morbidity and mortality with EVAR compared to open repair.² However, there are potential complications with this technique including mechanical problems such as kinking, fracture or migration of the stent, and 'endoleak'. Long term surveillance with imaging studies is therefore required to detect any late complications that may require intervention.

Endoleak is the persistent flow of blood within the aneurysm sac and occurs in approximately 20% of cases.² There are 5 different types of endoleak. Type 1 endoleak involves blood flow outside the graft but inside the sac, arising from either the proximal or

distal end of the graft; type 2 endoleak describes persistent back flow of blood from aortic side branches, commonly the lumbar or inferior mesenteric arteries. Leakage into the sac which arises from the join between stent components is termed a type 3 leak. Types 4 and 5 leaks are less common and involve sac expansion due to increased porosity of graft material, or with no clear point of leakage (endotension), respectively.³

Routine imaging is required post-operatively to detect endoleak because of the risk that persistent flow in the aneurysm sac may predispose to rupture.⁴ Type 1 and 3 leaks in particular are associated with a high pressure leak into the abdominal aortic aneurysm (AAA) sac and therefore are at significant risk of rupture.⁵

Duplex Ultrasound Scanning (DUSS) and Computerised Tomography (CT) are the most common methods used for endoleak detection. Although initial reports comparing DUSS with CT suggested that sensitivity and specificity were comparable,^{6,7} more recently, doubt has arisen as to the reliability of

*Corresponding author. R.M. Sandford, 151 Clarendon Park Road, Clarendon Park, Leicester LE2 3AJ, UK.
E-mail address: rs173@le.ac.uk

DUSS alone.^{8–10} In particular, DUSS has been found to have poor diagnostic accuracy in relation to specific types of endoleaks.¹¹

DUSS is the main imaging modality used in our centre in the routine follow-up of patients following EVAR. If DUSS is felt to be inadequate or an abnormality is detected, CT scan is arranged.

In order to guide post operative follow-up, we evaluated the performance of DUSS in the detection of endoleak in our centre using CT as the 'gold standard'.

Methods

Imaging was retrospectively reviewed for 310 consecutive patients undergoing endovascular aneurysm repair at a single centre between 30/03/94 and 08/10/05. Patients were followed up after EVAR in a nurse led clinic and underwent six monthly clinical examination and duplex ultrasound scan. Colour flow DUSS was performed by a trained Vascular Technician using a Phillips HDI 5000 ultrasound machine. No contrast was used. If an abnormality was found on DUSS, or views were inadequate, patients underwent computed tomography (CT) scan, using intravenous contrast and a Phillips Secura single slice spiral CT. Duplex ultrasound scan data was retrieved from the Vascular Studies Unit database. Data regarding time since operation, presence or absence of endoleak and any additional information gained from the scan (eg. regarding adequacy of views) were recorded. Records of CT scan reports were retrieved from computerised hospital radiology records and the same data recorded.

All patients having undergone concurrent DUSS and CT scans were included in the analysis. Concurrent scans were defined as having occurred within 6 months of each other.

The imaging modalities were compared with respect to their detection of endoleak, using CT as the

'gold standard'. Sensitivity (defined as the probability that the test is positive if the patient has an endoleak) and specificity (the probability that the test is negative if the patient does not have an endoleak) of DUSS compared with CT were calculated. Positive and negative predictive values (the percentage of tests which accurately identified patients with and without endoleak respectively) were also calculated. Kappa statistics, which take into account the proportion of agreement due to chance, were used to give a measure of agreement between the two tests (SPSS 9.0 Package). A low Kappa represents a poor level of agreement between the tests, whereas a Kappa value close to 1 implies a near perfect agreement. Likelihood ratios were also calculated to reflect the degree of increased suspicion of endoleak following a positive DUSS.

Results

Three hundred and ten patients underwent endovascular aneurysm repair (EVAR) at the Leicester Royal Infirmary over an 11 year period between 30/03/94 and 08/10/05. Patients were followed up using a combination of DUSS and CT scans. In total, there were 1352 DUSS scans performed, and 520 CT scans. There were 244 paired scans, i.e. both DUSS and CT performed within six months of each other and these have been used for further analysis.

Detection of endoleak varied between the two imaging modalities (see Table 1). DUSS failed to detect a number of endoleaks at all time points compared with CT. Sensitivity of DUSS was found to be 64% (range 33–100%) however specificity was much better with a value of 91% (range 73–100%) (Table 2).

Positive predictive values were calculated and ranged from 33%–100% but negative predictive values were much more reliable with values of 91–100% (Table 3). Kappa statistics were used to describe the level of agreement between the two tests and are

Table 1. Detected endoleaks by DUSS compared with CT

Time point post surgery	Number of patients	Outcome of DUSS		Outcome of CT		True positive on DUSS (%)	False positive on DUSS (%)	True negative on DUSS (%)	False negatives on DUSS (%)
		L	NL	L	NL				
3 months	73	7	66	10	63	3 (43)	4 (57)	63 (95)	3 (5)
6 months	30	3	27	4	26	2 (67)	1 (33)	26 (96)	1 (4)
12 months	45	6	39	9	36	2 (33)	4 (67)	36 (92)	3 (8)
24 months	50	7	43	10	40	4 (57)	3 (43)	40 (93)	3 (7)
36 months	25	3	22	5	20	1 (33)	2 (67)	20 (91)	2 (9)
48 months	17	6	11	5	12	2 (33)	4 (67)	11 (100)	0
60 months	4	1	3	1	3	1 (100)	0	3 (100)	0
Total	244	33	211	44	200	15 (45)	18 (55)	199 (94)	12 (6)

Where L = leak seen, and NL = no leak seen.

Table 2. Sensitivity and Specificity of DUSS compared with CT

Time point post surgery	Sensitivity (%)	95% Confidence interval	Specificity (%)	95% Confidence interval
3 months	50	22–77%	94	87–97%
6 months	67	25–92%	96	85–99%
12 months	40	14–73%	90	80–95%
24 months	57	29–81%	93	84–97%
36 months	33	8–74%	91	76–97%
48 months	100	42–100%	73	52–87%
60 months	100	27–100%	100	52–100%
Mean	64		91	

Where

$$\text{Sensitivity} = \frac{\text{number of patients with a true positive DUSS}}{\text{number of patients with a positive CT}}$$

and

$$\text{Specificity} = \frac{\text{number of patients with a true negative DUSS}}{\text{number of patients with a negative CT}}$$

given in Table 4; overall there was a fair to moderate agreement between the scans. Likelihood ratios were calculated (see Table 5) and showed a 81% likelihood of endoleak with a positive DUSS and a 96% likelihood of no endoleak with a negative DUSS.

Although DUSS did miss a number of endoleaks, these were all type 2 leaks with the exception of one patient. In this case, a type 1 leak had previously been visualised on DUSS which was not detected on this occasion. However, due to an increase in sac diameter and abdominal tenderness, a CT was arranged which was able to demonstrate the ongoing type I leak.

Of the 1352 DUSS performed, 151 (11%) reported difficult views due to either increased bowel gas or

Table 3. Positive and Negative predictive value of DUSS compared with CT

Time point post surgery	Positive predictive value	95% Confidence interval	Negative predictive value	95% Confidence interval
3 months	43%	19–71%	96%	89–98%
6 months	67%	25–92%	96%	85–99%
12 months	33%	12–65%	92%	82–97%
24 months	57%	29–81%	93%	84–97%
36 months	33%	8–95%	91%	76–97%
48 months	33%	12–65%	100%	80–100%
60 months	100%	27–100%	100%	52–100%
Mean	52%		95%	

Where

$$\text{Positive predictive value} = \frac{\text{Number who have positive CT}}{\text{Number who have positive DUSS}}$$

and

$$\text{Negative predictive value} = \frac{\text{Number who have a negative CT}}{\text{Number who have a negative DUSS}}$$

Table 4. Correlation of DUSS with CT by Kappa statistics

Time point post surgery	Kappa statistic	Standard error	Level of agreement
3 months	0.34	0.15	Fair
6 months	0.57	0.23	Moderate
12 months	0.25	0.15	Fair
24 months	0.46	0.15	Moderate
36 months	0.24	0.20	Fair
48 months	0.35	0.19	Fair
60 months	1	0	Very good
Overall	0.36	0.09	Fair

Where a Kappa value of <0.2 = poor agreement, 0.2–0.4 = fair agreement, 0.4–0.6 = moderate agreement, 0.6–0.8 = good agreement, 0.8–1 = very good agreement, 1 = perfect agreement.

obesity. The proportion of scans which reported poor views was higher immediately post operatively than subsequent scans, affecting 19 of 99 (19%) pre-discharge scans.

Discussion

Detection and management of endoleak remains a major drawback of endovascular aneurysm repair. We evaluated current practice at a single centre in terms of endoleak detection by two imaging modalities, DUSS and CT. Duplex ultrasound detected a total of 33 endoleaks, of which 15(45%) were found to be 'true positive' results when compared with CT. One hundred and ninety-nine patients (94%) were correctly identified as free from endoleak on DUSS. Ultrasound was therefore found to have very high specificity in the detection of endoleak (91%), but lower sensitivity (67%). Of the endoleaks missed on DUSS, all except one were type II leaks which represent a low pressure leak with a low risk of aneurysm rupture.¹²

Reports of the sensitivity of DUSS compared with CT vary. Some authors have found ultrasound to be very sensitive with detection rates as high as 81%,^{6,11,13} however most studies report similar results to our own with sensitivities ranging from 25%⁸ to 43%.⁹ All reported specificities are high, ranging from 89–96%.^{6,8,9,12}

CT scan was taken to be the 'gold standard' in this study and this introduces a potential source of bias if, in fact, CT is imperfect. This may be confounded by the time delay between DUSS and CT scan, as new endoleaks may have developed or previously identified leaks sealed during this lag time. This may give the impression of a poor performance of DUSS compared with CT.

In addition, patients with a positive or unclear DUSS underwent CT as a result of clinical indication

Table 5. Likelihood ratios

Prevalence of endoleak	Pre-test odds of true result	LR+	LR–	Post test odds of true result	Post test probability of true result
6.1%	0.64	6.7	37	If test +ve 4.3 If test –ve 23.7	If test +ve 81% If test –ve 96%

Where:

$$\text{Prevalence} = \frac{\text{number of true positives} + \text{false negatives}}{\text{Total number of scans}}$$

$$\text{Pre-test odds} = \frac{\text{prevalence}}{(1 - \text{prevalence})}$$

$$\text{LR+} = \text{Likelihood ratio of endoleak if DUSS positive} = \frac{\text{sensitivity}}{(1 - \text{specificity})}$$

$$\text{LR–} = \text{Likelihood ratio of no endoleak if DUSS negative} = \frac{(1 - \text{sensitivity})}{\text{Specificity}}$$

$$\text{Post-test odds} = \text{pre-test odds} \times \text{likelihood ratio}$$

$$\text{Post-test probability} = \frac{\text{post-test odds}}{\text{post test odds} + 1}$$

rather than routine protocol, and this is likely to have shortened the time delay between scans. This may result in a greater observed DUSS sensitivity but lesser specificity among patients with a positive DUSS.

Sensitivity of DUSS is also known to be affected by several factors such as bowel gas, body habitus and operator experience,⁸ and this may account for some degree of error. In spite of the low sensitivity of DUSS, only one type I endoleak was missed, and this patient was referred for CT on the basis of an increase in sac size detected on DUSS.

One potential way to improve the sensitivity of DUSS is through the use of contrast media, Henao *et al.* demonstrated increased endoleak detection with contrast-enhanced duplex scanning, and in fact detected some endoleaks not seen on CT using this technique.¹⁴ The introduction of contrast-enhanced scans may therefore lead to greater reliance on ultrasound in the future.

The mortality benefit of EVAR is well documented,^{2,15,16} but the long term survival may be no better than open repair.¹⁷ This is largely due to the incidence of late complications such as endoleak and device migration. Type I and III endoleak are particularly associated with aneurysm rupture with a cumulative risk of up to 1% per year.⁵

The EVAR 1 trial reported 27 (5.1%) type I and 8 (1.5%) type III endoleaks during the 4 year follow up period. They also found 9 (1.7%) patients following EVAR developed late aneurysm rupture, 5 of whom died. During the same follow up period, only one patient died following rupture of their aneurysm after open repair.² This increased the hazard ratio for endovascular repair from 0.42 in the first six months

following surgery to 1.15 in the period from six months to 4 years.

In order to prevent late aneurysm rupture following EVAR, complications need to be reliably detected and corrected. The EUROSTAR data reported an 18% re-intervention rate at 20 months post EVAR,¹⁷ and this is in keeping with the EVAR 1 trial report of a 20% re-intervention rate after 4 years.²

EVAR is currently significantly more expensive than open repair with an additional cost of £110 000 per quality adjusted life year (QALY) reported by the EVAR 1 trial.¹⁸ Part of this additional cost is due to the long term surveillance required to detect late complications specific to endovascular repair. Ultrasound scan is much less expensive than CT scan and may therefore improve the cost benefit ratio of EVAR if used as the primary imaging modality for surveillance.

Computed tomography was used as the 'gold standard' in this study and therefore the finding of a lower sensitivity with DUSS is to be expected. However, we have found an acceptable rate of endoleak detection with this technique, using CT scan to clarify the nature of any abnormalities seen. In conclusion, we have found DUSS to be reliable in the detection of endoleak following endovascular aneurysm repair. Although the sensitivity of this technique may be poor in comparison with CT scan, no clinically significant leaks were missed, and routine use of DUSS has the added benefits of avoiding high doses of radiation and escalating costs. We therefore support this protocol in the long term surveillance of patients following endovascular aneurysm repair.

References

- 1 PARODI JC, PALMAZ JC, BARONE HD. Transfemoral intraluminal graft implantation for abdominal aortic aneurysm. *Ann Vasc Surg* 1991;5:491–497.
- 2 EVAR trial participants. Endovascular aneurysm repair versus open repair in patients with abdominal aortic aneurysm (EVAR trial 1): randomised controlled trial. *Lancet* 2005;365(9478):2179–2186.
- 3 WHITE GH, MAY J, WAUGH RC, CHAUFOR X, YU W. Type III and IV endoleak: toward a complete definition of blood flow in the sac after endoluminal AAA repair. *J Endovasc Surg* 1998;5(4):305–309.
- 4 MATSUMURA JS, MOORE WS. Clinical consequences of periprosthetic leak after endovascular repair of abdominal aortic aneurysm. Endovascular Technologies Investigators. *J Vasc Surg* 1998;27:606–613.
- 5 HARRIS PL, VALLABHANENI SR, DESGRANGES P, BECQUEMIN J-P, VAN MARREWIK C, LAHEIJ RJE. Incidence and risk factors of late rupture, conversion and death after endovascular repair of infrarenal aortic aneurysms: the EUROSTAR experience. *J Vasc Surg* 2000;32:739–749.
- 6 WOLF YG, JOHNSON BL, HILL BB, RUBIN GD, FOGARTY TJ, ZARINS CK. Duplex ultrasound scanning versus computed tomographic angiography for postoperative evaluation of endovascular abdominal aortic aneurysm repair. *J Vasc Surg* 2000;32(6):1142–1148.
- 7 SATO DT, GOFF CD, GREGORY RT *et al.* Endoleak after aortic stent graft repair: diagnosis by color duplex ultrasound scan versus computed tomography scan. *J Vasc Surg* 1998;28(4):657–663.
- 8 ELKOURI S, PANNETON JM, ANDREWS JC *et al.* Computed tomography and ultrasound in follow-up of patients after endovascular repair of abdominal aortic aneurysm. *Ann Vasc Surg* 2004;18(3):271–279.
- 9 RAMAN KG, MISSIG-CARROLL N, RICHARDSON T, MULUK S, MAKAROUN MS. Color-flow duplex ultrasound scan versus computed tomographic scan in the surveillance of endovascular aneurysm repair. *J Vasc Surg* 2003;38(4):645–651.
- 10 MCWILLIAMS RG, MARTIN J, WHITE D *et al.* Detection of endoleak with enhanced ultrasound imaging: comparison with biphasic computed tomography. *J Endovasc Ther* 2002;9(2):170–179.
- 11 ASHOK R, BROWN LC, RODWAY A, CHOKE E, THOMPSON MM, GREENHALGH RM *et al.* Color duplex ultrasonography is insensitive for the detection of endoleak after aortic endografting: a systematic review. *J Endovasc Ther* 2005;12(3):297–305.
- 12 VAN MARREWIK C, BUTH J, HARRIS PL, NORRGREN L, NEVELSTEEN A, WYATT MG. Significance of endoleaks after endovascular repair of abdominal aortic aneurysms: the EUROSTAR experience. *J Vasc Surg* 2002;35(3):461–473.
- 13 ABURAHMA AF, WELCH CA, MULLINS BB, DYER B. Computed tomography versus color duplex ultrasound for surveillance of abdominal aortic stent-grafts. *J Endovasc Ther* 2005;12(5):568–573.
- 14 HENAO EA, HODGE M, FELKAI DD, MCCOLLUM CH, NOON GP, LIN PH *et al.* Contrast-enhanced Duplex surveillance after endovascular abdominal aortic aneurysm repair: improved efficacy using a continuous infusion technique. *J Vasc Surg* 2006;43(2):259–264.
- 15 PRINSEN M, VERHOVEN EL, BUTH J, CUYPERS PW, VAN SAMBEEK MR, BALM R *et al.* Dutch Randomised Endovascular Aneurysm Management (DREAM) Trial Group. *N Engl J Med* 2004;351(16):1607–1618.
- 16 LAHEIJ RJE, BUTH J, HARRIS PL, MOLL FL, STELTER WJ, VERHOVEN ELG, on behalf of the EUROSTAR collaborators. Need for secondary interventions after endovascular repair of abdominal aortic aneurysms, Intermediate-term follow-up results of a European collaborative registry. *Br J Surg* 2000;87(12):1666–1673.
- 17 BLANKENSTIJN JD, DE JONG SECA, PRINSEN M, VAN DER HAM A, BUTH J, VAN STERKENBURG SMM *et al.* for the Dutch Randomised Endovascular Aneurysm Management (DREAM) Trial Group. Two-Year Outcomes after Conventional or Endovascular Repair of Abdominal Aortic Aneurysms. *N Engl J Med* 2005;352:2398–2405.
- 18 MICHAELS JA, DRURY D, THOMAS SM. Cost effectiveness of endovascular abdominal aneurysm repair. *Br J Surg* 2005;92(8):960–967.

Accepted 23 May 2006

Available online 26 July 2006